Remarks

Upon entry of the foregoing amendment, claims 1-24 are pending in the application, with claims 1-3, 19, and 22 being the independent claims. Claims 1-3, 19, and 22 are sought to be amended to clarify that the thrombin layer is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer, as discussed during the Examiner Interview described below. Support for the amendments to the claims may be found in the specification, *inter alia*, at paragraphs [0008]-[0011], [0013]-[0015], [0019], [0030], [0032]-[0034], [0043], [0045], [0046], [0059] and [0080], and in the claims as originally filed. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendments and the following remarks, Applicants respectfully request that the Office reconsider all outstanding rejections and that they be withdrawn.

Examiner Interview

Applicants thank the Examiner for the courtesies extended during the interview conducted with Applicants' representatives on July 23, 2009. During the interview, Applicants' representatives discussed with the Examiner the outstanding claim rejections. After reviewing the references cited in the Office Action of April 1, 2009, the Examiner acknowledged that none of the cited references teach the present invention. The Examiner further indicated that she would be withdrawing the rejections under 35 U.S.C. §§ 102 and 103.

Rejection under 35 U.S.C. § 102(b)

The rejection of claims 1-3, 11-16, 19, and 22 under 35 U.S.C. § 102(b) as allegedly being anticipated by Macphee *et al.*, WO 99/59647 ("the WO reference") is respectfully traversed. Originally filed claims 1-3, 11-16, 19, and 22 each relate to "a hemostatic dressing . . . wherein the thrombin layer is noncoextensive with the first fibrinogen layer and/or the second fibrinogen layer." The Office alleges that the specification describes the term "noncoextensive" in such a manner as to encompass a hemostatic dressing in which the thrombin layer is coextensive with the first fibrinogen layer and/or the second fibrinogen layer. *See* Office Action, page 3. As such, the Office asserts that the WO reference anticipates the claimed hemostatic dressing because the WO reference allegedly "teaches a haemostatic multilayer bandage that comprises a thrombin layer between two fibrinogen layers . . . ." *Id.* at pages 4 and 5.

1. The term "noncoextensive" means not coextensive.

The Office asserts that "the word 'about' provides a latitude for 95% coextensive such that the thrombin layer is coextensive with the first and/or the second layer." Office Action, page 3. Applicants respectfully disagree with the Office's definition of the term "noncoextensive."

First, a noncoextensive thrombin layer that is "about 95% coextensive" is not "coextensive" with the first fibrinogen layer and/or the second fibrinogen layer. Construing the term "noncoextensive" to encompass the scope of coextensive would be inconsistent with the specification's description of the invention and would be nonsensical. The specification indicates that the use of noncoextensive thrombin and fibrinogen layers yields a hemostatic dressing that "offers various advantages as

compared with conventional dressings." Specification, page 2, ¶ [0030]. Specifically, "[b]y using a thrombin layer that is noncoextensive with one or both fibrinogen layers, the dressings of the invention are less likely to become delaminated at their edges, thus rendering the dressings more durable and easier to handle than conventional dressings. In addition, such dressings are more amenable to large-scale manufacturing and provide for better control of the amount of thrombin dispensed in the dressing." *Id.*; *see also id.*, Examples 1 and 2. Accordingly, in view of the nature of the invention, the term "noncoextensive" cannot be construed to encompass the scope of coextensive.

Second, the Office's construction of the term "about" is inconsistent with the applicants' explicit definitions of the claim terms "noncoextensive" and "coextensive." The specification indicates that "[a] thrombin layer that is 'coextensive' with a fibrinogen layer provides full coverage of the fibrinogen layer and is coextensive with 100% of the surface area of the fibrinogen layer." Specification, page 2, ¶ [0019]. The prefix "non" means "not." *The American Heritage College Dictionary*, page 927 (3rd ed., 1993). A person of ordinary skill in the art would understand that the term "noncoextensive" means "not coextensive," and a thrombin layer that is noncoextensive with a fibrinogen layer is not coextensive with the surface area of the fibrinogen layer. Construing the term "noncoextensive" to encompass coextensive would therefore impermissibly eliminate the term "noncoextensive" from the claims.

Accordingly, for at least these reasons, applicants respectfully assert that the originally filed claims do not encompass a hemostatic dressing in which the thrombin layer is coextensive with the first and the second fibrinogen layer.

However, solely to expedite prosecution and not in acquiescence to the Office's rejections, applicants have amended independent claims 1-3, 19, and 22 to recite "not coextensive," as discussed during the Examiner's interview, in order to clarify that the claimed hemostatic dressing has a thrombin layer that is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer.

2. The WO reference does not anticipate claims 1-3, 11-16, 19, and 22.

The WO reference does not anticipate claims 1-3, 19, and 22 because the WO reference does not teach each and every limitation of claims 1-3, 19, and 22.

Claims 1-3 are directed to, *inter alia*, a hemostatic dressing that contains a first fibrinogen layer, a thrombin layer adjacent to the first fibrinogen layer, and a second fibrinogen layer adjacent to the thrombin layer, wherein the thrombin layer is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer. Claims 19 and 22 are directed to, *inter alia*, a method of preparing such a hemostatic dressing. The WO reference does not teach each and every limitation of the rejected claims because the WO reference does not teach, *inter alia*, a hemostatic dressing that has a thrombin layer that is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer. The Examiner has acknowledged in the Office Action as well as during the Examiner's interview that the WO reference "fails to teach the claimed limitation of non-coextensive thrombin layer with the first or second fibrinogen layer . . . ." Office Action, page 5. Accordingly, the WO reference does not anticipate claims 1-3, 19, and 22 because the WO reference does not teach each and every element as set forth in claims 1-3, 19, and 22.

Claims 11-16 depend from independent claims 1, 2, and/or 3 and thus contain all the limitations of the claim(s) from which they depend. As such, these dependent claims are patentable for at least the reasons set forth above for claims 1-3.

Rejections under 35 U.S.C. § 102(e)

The rejection of claims 1-3, 11-16, 19, and 22 under 35 U.S.C. § 102(e) as allegedly being anticipated by Macphee *et al.*, U.S. Patent Number No. 6,762,336 ("the '336 patent") is respectfully traversed. The Office asserts that the '336 patent anticipates the claimed hemostatic dressing because the '336 patent allegedly teaches "a haemostatic multilayer bandage that comprises a thrombin layer between two fibrinogen layers . . . ." Office Action, page 5.

The '336 patent issued from the U.S. National Phase Application of International Patent Application No. PCT/US99/10952 (*i.e.*, the WO reference). The '336 patent therefore has the same disclosure as the WO reference. As such, for at least the reasons discussed above for the WO reference, claims 1-3, 11-16, 19, and 22 are not anticipated by the '336 patent.

Rejection under 35 U.S.C. § 103(a)

The rejection of claims 4-7, 20, 23, and 24 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '336 patent or the WO reference in view of Yewdall *et al.*, U.S. Patent Application No. 2006/0179793 ("Yewdall") is respectfully traversed.

First, submitted herewith is a Statement of Common Ownership which establishes that the present application and the '336 patent were, at the time the present invention was made, owned by, or subject to an obligation of assignment to, the

American National Red Cross. Therefore, under 35 U.S.C § 103(c)(1), the '336 patent is disqualified as prior art against the present application.[1]

Second, applicants respectfully assert that claims 4-7, 20, 23, and 24 would not have been obvious in view of the WO reference and Yewdall because Yewdall does not cure the deficiencies of the WO reference. Furthermore, the cited references do not provide a rationale, either alone or in combination, to modify their teachings to arrive at the present invention.

In proceedings before the United States Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *See In re Piasecki*, 745 F.2d 1468, 1471-73 (Fed. Cir. 1984). As set forth in *Graham v. John Deere Co. of Kansas City*, "[u]nder § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined." 383 U.S. 1, 17 (1966). This has been the standard for 40 years, and remains the law today. *See KSR*, 550 US at 3. If, after these criteria are considered, and the evidence indicates that the claimed invention would have been obvious over the prior art, it may be said that a *prima facie* case of obviousness has been established.

Claims 4-7 depend from independent claims 1-3. Thus, claims 4-7 are directed to, *inter alia*, a hemostatic dressing that has a thrombin layer that is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer. Claim 20 depends from

[1] As discussed above, the '336 patent has the same disclosure as the WO reference. Therefore, even if the '336 patent was not disqualified as prior art against the present application, for at least the reasons set forth below for the WO reference and Yewdall, claims 1-3, 11-16, 19, and 22 would not have been obvious in view of the '336 patent and Yewdall.

independent claim 19, and claims 23 and 24 depend from independent claim 22. Therefore, claims 20, 23, and 24 are directed to, *inter alia*, a method of preparing such a hemostatic dressing.

As discussed above, the WO reference does not teach a hemostatic dressing that has a thrombin layer that is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer as required by claims 4-7. Furthermore, the WO reference does not teach a method of preparing such a hemostatic dressing as required by claims 20, 23, and 24.

Yewdall does not cure the deficiencies of the WO reference. The Examiner asserts that Yewdall describes a bandage arrangement "wherein at least the top fibrinogen layer extends over the sides of the sandwich." Office Action, page 7. Applicants respectfully disagree. Applicants respectfully assert that Yewdall does not teach that "the top fibrinogen layer extends over the sides of the sandwich."

Figure 1 of Yewdall is reproduced below:

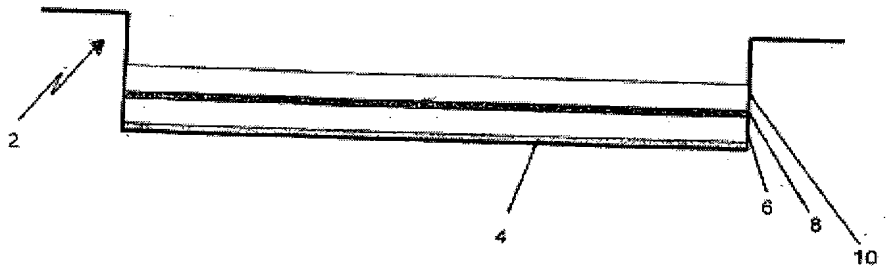

Figure 1 of Yewdall is a cross-sectional schematic representation of "a container for use as a mould in which a haemostatic sandwich bandage is formed and also one form of such a bandage within the mould." Yewdall, paragraph [0044]. Element 2 in the

diagram is an outline of the body of the container. *Id.* Elements 4, 6, 8, and 10 comprise the bandage within the container. *Id.* Element 4 is an absorbable bandage material. *Id.* Elements 6, 8, and 10 are fibrinogen, thrombin, and fibrinogen layers, respectively. *Id.* Figure 1 of Yewdall depicts the fibrinogen layers as adjacent to and *coextensive* with the thrombin layer. Yewdall indicates that the top fibrinogen layer (*i.e.*, element 10) is the side (surface) of the bandage that contacts the wound; there is nothing in Figure 1 or the Yewdall specification that teaches or suggests that the top fibrinogen layer extends beyond the surface area of the thrombin layer that it contacts. *See id.* In other words, nothing in Yewdall teaches or suggests a thrombin layer that is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer. Yewdall does not teach a bandage arrangement "wherein at least the top fibrinogen layer extends over the sides of the sandwich," or in which the thrombin layer is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer. Applicants respectfully assert that Yewdall likewise does not teach the claimed hemostatic dressing or a method of preparing such a hemostatic dressing.

Accordingly, for at least these reasons, claims 4-7, 20, 23, and 24 would not have been obvious in view of the WO reference and Yewdall because the cited references do not disclose the present invention, either alone or in combination, or provide a rationale, either alone or in combination, to modify their teachings to arrive at the present invention. For example, there is no discussion in the cited references regarding the advantages of making the claimed modification. Neither the WO reference nor Yewdall describe how use of a thrombin layer that is not coextensive with the first and/or the second fibrinogen layer is advantageous because the resultant dressing is less likely to

become delaminated at their edges, thus rendering the dressing more durable and easier to handle. *See* specification, page 2, ¶ [0030]. In addition, neither of the cited references indicates that such dressings are more amenable to large-scale manufacturing and provide for better control of the amount of thrombin dispensed in the dressing. *Id.*

The rejection of claims 8-10, 17, and 18 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '336 patent or the WO reference in view of Macphee *et al.*, U.S. Patent Number No. 6,117,425 ("the '425 patent") is respectfully traversed.

As discussed above, the '336 patent does not qualify as prior art against the present application under 35 U.S.C. § 103(c) against the present application.[2] Applicants also respectfully assert that claims 8-10, 17, and 18 would not have been obvious in view of the WO reference and the '425 patent because the '425 patent does not cure the deficiencies of the WO reference. Furthermore, the cited references do not provide a rationale, either alone or in combination, to modify their teachings to arrive at the present invention.

Claims 8-10, 17, and 18 depend from independent claims 1-3. Thus, claims 8-10, 17, and 18 are directed to, *inter alia*, a hemostatic dressing that has a thrombin layer that is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer. In contrast, as discussed above, the WO reference does not teach the claimed hemostatic dressing as required by claims 8-10, 17, and 18.

The '425 patent does not cure the deficiencies of the WO reference. The Office states that the '425 patent teaches "tissue sealant production where the ready to use

[2] As discussed above, the '336 patent has the same disclosures as the WO reference. Therefore, even if the '336 patent was not disqualified as prior art against the present application, for at least the reasons set forth below for the WO reference and the '425 patent, claims 8-10, 17, and 18 would not have been obvious in view of the '336 patent and the '425 patent.

bandage has a backing layer and dry powder materials comprising effective amount of thrombin and fibrinogen and the outer adhesive material is attached to the skin such that it directly forms a fibrin clot over the wound." Office Action, page 8 (internal citations omitted). However, the '425 patent does not teach a hemostatic dressing that has a thrombin layer that is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer as required by claims 8-10, 17, and 18. The '425 patent therefore does not cure the deficient teachings of the WO reference.

Applicants respectfully disagree with the Office's statement that it would have been obvious to "employ thrombin as a dry powdered material, which appears as spots, dots or other patterns of choice . . . ." *Id.* The Office Action does not point to any disclosure in any of the cited references to support such a proposition. Furthermore, after reviewing the '425 patent, the Examiner affirmed during the interview that the '425 patent does not support such a proposition. Indeed, none of the cited references, even in combination, provides a reason to use thrombin in such a configuration, let alone in a configuration such that the thrombin layer is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer, as claimed.

Accordingly, for at least these reasons, claims 8-10, 17, and 18 would not have been obvious in view of the WO reference and the '425 patent because the cited references do not teach or suggest the present invention, either alone or in combination. Furthermore, claims 8-10, 17, and 18 would not have been obvious in view of the WO reference and the '425 patent because the cited references do not provide a rationale, either alone or in combination, to modify their teachings to arrive at the present

invention. For example, there is no discussion in the cited references regarding the advantages of making the claimed modification. Neither the WO reference nor the '425 patent describe how use of a thrombin layer that is not coextensive with the first and/or the second fibrinogen layer is advantageous because the resultant dressing is less likely to become delaminated at their edges, thus rendering the dressing more durable and easier to handle. *See* specification, page 2, ¶ [0030]. In addition, neither of the cited references indicates that such dressings are more amenable to large-scale manufacturing and provide for better control of the amount of thrombin dispensed in the dressing. *Id.*

Double patenting rejection

Claims 1-3, 11-16, 19, and 22 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of the '336 patent. Applicants respectfully traverse this rejection. Applicants respectfully assert that the claims of the '336 patent neither anticipate nor render obvious the presently claimed invention.

As noted in MPEP § 804(III), "a double patenting rejection must rely on a comparison with the *claims* in an issued or to be issued patent, whereas an anticipation or obviousness rejection based on the same patent under 35 U.S.C. 102(e)/ 103(a) relies on a comparison with what is disclosed (whether or not claimed) in the same issued or to be issued patent." (emphasis added; formatting removed). Furthermore, inventions based on the identification or selection of a specific material or compound with particularly desirable properties within a previously claimed genus of such materials or compounds are patentably distinct from the prior claimed subject matter. *See e.g.*, *In re Kaplan*, 789 F.2d 1574, 1578, 1580 (Fed. Cir. 1986) (prior generic patent claim did not invalidate

claim to later selected species for double patenting); *see also In re Ruschig*, 343 F.2d 965, 974-75 (C.C.P.A. 1965) (prior generic disclosure did not anticipate later selected species under 35 U.S.C. § 102); *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1340 (Fed. Cir. 2003) ("Improvement and selection inventions are ubiquitous in patent law . . ."); *In re Baird*, 16 F.3d 380, 383 (Fed. Cir. 1994) (prior generic disclosure did not render later selected species obvious under 35 U.S.C. § 103).

As described above, claims 1-3 are directed to, *inter alia*, a hemostatic dressing that has a thrombin layer that is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer. Claims 19 and 22 are directed to, *inter alia*, a method of preparing such a hemostatic dressing. In contrast, claims 1-9 of the '336 patent are *not* directed to a hemostatic dressing that has a thrombin layer that is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer as required by claims 1-3, 19, and 22 of the present application. Nothing in the '336 patent claims even suggests the use of a thrombin layer that is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer. Furthermore, the Examiner has acknowledged in the Office Action as well as during the Examiner's interview that the claims of the '336 patent "differ from the instant claims in that the patented claims do not state that the thrombin is noncoextensive with first and/or second layer." Office Action, page 3. In the absence of an express or inherent disclosure of a thrombin layer that is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer, the instant claims simply cannot be anticipated. Likewise, there is no disclosure in the prior claims that provides a reason to make a dressing having a thrombin layer that is not coextensive with the first fibrinogen layer and/or the second fibrinogen layer. Accordingly, as claims 1-9 of the '336 patent

do not teach every element set forth in claims 1-3, 19, and 22 of the present application, claims 1-9 of the '336 patent do not anticipate or render obvious claims 1-3, 19, and 22 of the present application, and the double patenting rejection is therefore improper.

Claims 11-16 depend from independent claims 1, 2, and/or 3 and thus contain all the limitations of the claim(s) from which they depend. As such, these dependent claims are patentable for at least the reasons set forth above for claims 1-3.

For at least the above reasons, Applicants respectfully request that the outstanding rejections be reconsidered and withdrawn.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Office reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Office believes, for any reason, that personal communication will expedite prosecution of this application, the Office is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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